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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/293,835	04/19/1999	JAMES C. KENNEDY	067286/136/D	5426

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FOLEY & LARDNER
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EXAMINER	
RAMACHANDRAN, UMAMAHESWARI	
ART UNIT	**PAPER NUMBER**
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/293,835	KENNEDY ET AL.	
	Examiner	Art Unit	
	Umamaheswari Ramachandran	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52,53 and 56-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52,53 and 56-63* is/are rejected.

7)☒ Claim(s) *53, 56 and 60* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 52, 53, 56-63 are pending.

Response to Remarks

The examiner notes the receipt of the amendments and remarks received in the office on 12/01/2006. Claims 1-51, 54-55 have been canceled and 52, 56, 60, 62-63 have been amended. Claims 52, 53, 56-63 are currently pending.

The rejection under 35 U.S.C 103 for claims 1, 15, 28, 31-35, 62, 63 is withdrawn due to the cancellation of claims 1-51 and amendment of claims 52, 56, 60, 62-63. The claims are subjected to new grounds of rejection under 35 USC 112 first paragraph.

Claim Objections

Claim 53 is objected to, as it is dependent upon a rejected claim.

Claims 56 and 60 are objected to because of the following informalities: Claim 56, line 3, and claim 60, line 3 is typed as "or protoporphyrin" instead of "of protoporphyrin". Appropriate correction is required.

Claim Rejections. 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52, 56-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating onychomycosis with 5-ALA, does not reasonably provide enablement for all compounds that fall within the scope of the term "a precursor of protoporphyrin IX." The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

In particular, the specifications fail to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404, Fed. Cir. 1988. The court sets forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex part Forman, 230 USPQ 546 (BDApls 1986) at 547 the court recited eighth factors: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance provided, 3) working examples, 4) the nature of the invention, 5) the state of the prior art, 6) the relative skill of those in the art 7) the predictability of the art, and 8) the breadth of the same.

Applicant fails to set forth the criteria that define a clear genus or group of compounds that may be used in the instant methodology.

(1) The nature of the invention: The invention is directed to the use of a precursor of protoporphyrin IX that results in accumulation of protoporphyrin IX in the treatment of a disorder associated with a fungus of exogenous origin and in the treatment of onychomycosis. The specification describes the use of aminolevulinic acid, which is only one type of precursor of protoporphyrin IX.

(2) The state of the prior art: The state of art in determining a precursor of protoporphyrin IX is only limited to such compounds enumerated in the heme biosynthetic pathway. The art does not describe the penultimate functional or chemical characteristics of such compounds that can possess the claimed property. The art

seems to lack a teaching for identifying the entire genus of compounds that are a precursor of protoporhyrin IX and result in acumulation of protoporphyrin IX. There is no evidence in the art that aminolevulinic acid is the penultimate compound representing all precursors of protoporphyrin IX resulting in accumulation of protoporphyrin IX. Therefore, the state of art is unpredictable, because there is no evidence in the art to ascertain the entire scope of compounds claimed as a precursor of protoporphyrin IX and their ability to treat a disorder associated with a fungus of exogenous origin and in the treatment of onychomycosis.

(3) The relative skill of those in the art: The relative skill of those in the art is high and include such artisans in the art of pharmacology, radiology, and clinical medicine.

(4) The unpredictability of the art: The nature of the applying pharmacological modalities to treat a pathological condition is unpredictable, because there exists substantial inter-patient variability. For example, attention is drawn to Bauer at Pharmacotherapy, A Pathophysiologic Approach, 2nd ed. page 15, Ist para, (already of record, filed 6/2004) which states "clinicians should never assume that a serum concentration within the therapeutic range will be safe and effective for every patient." Accordingly, there is no predictability in the art as to identifying the suitable precursor, or the suitable doses thereof that can cause the accumulation of protoporphyrin IX in the treatment of onychomycosis.

(5) The amount of direction or guidance presented: The specification discloses in methods of using aminolevulinic acid in treating onychomycosis. Accordingly, the direction provided in the specification does not describe all potential compounds in the

treatment of a disorder associated with a fungus of exogenous origin and in the treatment of onychomycosis.

(6) The presence or absence of working examples: A disclosure does not contain representative examples, which provide reasonable assurance to one skilled in the art that the all types of precursors of protoporphyrin IX would treat onychomycosis by resulting an accumulation of protoporphyrin IX in the desired tissue. Specification fails to provide adequate examples setting forth suitable compounds envisioned for the practice of the claimed methods. 5-ALA is the only compound exemplified in the specification.

(7) The breadth of the claims: The breadth of the claims are so broad as it can encompass various unrelated group of chemicals that can modulate for example heme biosynthesis, (where 5-ALA is a precursor of protoporphyrin IX) and that they do not share any common chemical core. The heme biosynthesis involves various intermediary steps wherein glycine is combined with succinyl coA to form 5-ALA. ALA respectively undergo series of synthetic steps sequentially producing tetrapyrroles, unporphyrinogen III, protoporphyrin IX and heme. Various types of unrelated compounds can modulate such pathway. However, specification does not clearly provide guidance as to which set of compounds has been envisioned to provide the therapeutic outcome instantly claimed.

(8) The quantity of experimentation necessary: Considering the above-mentioned factors and the fact that there are significant inter-individual variability in using a pharmacological modalities in human subjects, the nature of art is unpredictability, and the breadth of the claims; one of ordinary skill in the art would be burdened with undue

"experimentation study" to determine all the possible precursors of protoporphyrin IX in a method of treatment of a disorder associated with a fungus of exogenous origin and in the treatment of onychomycosis. Accordingly, the entire scope of the instant claims is not enabled.

Allowable Subject Matter

Claim 53 is free of the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER